



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,518	11/16/2001	William Fenical	6627-PA1022	7755
7590 06/27/2005			EXAMINER	
LISA A. HAILE, ESQ. GARY CARY WARE & FREIDENRICH LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	
			DATE MAILED: 06/27/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	09/991,518	FENICAL ET AL.			
Office Action Summary	Examiner	Art Unit			
	Irene Marx	1651			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the o	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period of the period for reply within the set or extended period for reply will, by statute any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	mely filed  ys will be considered timely.  the mailing date of this communication.  ED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 23 M	lay 2005.				
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is					
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.			
Disposition of Claims					
4) Claim(s) <u>1,17,18,20 and 25-32</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdraw	wn from consideration.				
5) Claim(s) is/are allowed.					
6) Claim(s) <u>1, 17-18, 20 and 25-32</u> is/are rejecte	d.				
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/o	r election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examine	er.				
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the	drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correct					
11) The oath or declaration is objected to by the Ex	caminer. Note the attached Office	e Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12)☐ Acknowledgment is made of a claim for foreign a)☐ All b)☐ Some * c)☐ None of:	priority under 35 U.S.C. § 119(a	)-(d) or (f).			
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the prior	•	ed in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
oee the attached detailed Office action for a list of the certified copies flot received.					
	•				
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) 1 Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	Paper No(s)/Mail D 5) Notice of Informal F	ate Patent Application (PTO-152)			
Paper No(s)/Mail Date	6) Other:	,			

Application/Control Number: 09/991,518

Art Unit: 1651

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/23/05 has been entered.

Claims 1, 17-18, 20 and 25-32 are being considered on the merits.

To conform with standard practice and for the sake of clarity, independent claims should be amended to start with --A-- and dependent claims to start with --The-. See, e.g., claim 26.

It is noted that at page 14, the specification indicates the basis for classifying *Salinospora* within *Micromonasporaceae* and that it has signature nucleotides not found in all other known *Micromonasporaceae* 16S rRNAs.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-18, 20 and 25-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is confusing and incomplete in reciting "method claim 1". Claim 1 is a product claim. In addition claim 20 lacks antecedent basis for "the growth media".

Claim 30 is confusing and incomplete in reciting "method claim 26-28". Claims 26-28 are product claims.

Claim 32 is confusing and incomplete in reciting "method claim 27". Claim 27 is a product claim. In addition claim 32 lacks antecedent basis for "the growth media".

Claims 18 and 31 are substantial duplicates.

To clarify the invention it is recommended that claims 17, 18, 25, 26, 29, etc. be amended to replace "the marine Actinomycete" with "the strain of *Salinospora*"

Application/Control Number: 09/991,518 Page 3

Art Unit: 1651

Claims 29 and 30 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must dependent on the base claim in the alternative. See MPEP § 608.01(n).

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 17-18, 20 and 25-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strains of *Salinospora*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 3 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

## SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

- 1. Identifies declarant.
- 2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
- 3. States that the deposited material has been accorded a specific (recited) accession number.
- 4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Application/Control Number: 09/991,518

Art Unit: 1651

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

- 6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
- 7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

This strain appears to be the type strain for the genus claimed.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/991,518

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651